

SOP#: ADCR-15

**Confidentiality Agreement for NCI Guest Clinical
Observers and Other Visitors**

Version #: 1.1

Next Review Date: 10/2022

Approved Date: 10/2020

Review Interval Period: Biennial

NCI Clinical Director Signature:

POLICY

Clinical research teams within the Center for Cancer Research (CCR), National Cancer Institute (NCI) intermittently host guest researchers, observers, students and other visitors who may be exposed to patient information, clinical research discussions and/or other personally identifiable information (PII). Patient safety, confidentiality and privacy are of critical importance and clinical research teams hosting visitors are expected to adhere to and ensure compliance with the form “Assuring Patient Confidentiality and Privacy at the NIH Clinical Center.” Any visitor or guest who is not a NIH staff member /contractor or not currently credentialed at the NIH Clinical Center must review and sign the form. The PI is responsible for ensuring that no visitor or guest is permitted to observe clinical research activities without first having signed the agreement form.

PURPOSE

To describe the process for the distribution, signature and tracking of the form “Assuring Patient Confidentiality and Privacy at the NIH Clinical Center” for guests, observers and other non-NIH persons exposed to PII regarding patients, research and other sensitive information.

For the purposes of this SOP, the term “guest” will mean any guest researcher, observer, student or other visitor being hosted by any NCI research team. This SOP does not apply to visitors/guests of patients.

RESOURCE

- Form: [Assuring Patient Confidentiality and Privacy at the NIH Clinical Center](#)
- NCI Contact:
 - NCI Deputy Clinical Director, Office of the Clinical Director, 240-760-6070
- NIH Clinical Center (CC) Contacts:
 - Authorization for Release of Information, Medicolegal Section, 301-496-3331
 - Media Interaction and Policy, CC Communications, 301-496-2563
 - Breach of Confidentiality, CC Privacy Officer, 301-496-4240

PROCEDURES

STEP 1: PI / Designee Reviews Form with Guest

- Prior to any guest (guest researcher, observer, student, visitor, volunteer, patient guest, etc.) who is not currently a NIH staff member/contractor or credentialed by the NIH Clinical Center, the PI leading the hosting clinical research team or their designee must ensure the form *Assuring Patient Confidentiality and Privacy at the NIH Clinical Center* is read and understood by the visitor.

STEP 2: Guest Signs Form

- Once the agreement form has been discussed with the guest, the guest must sign the form.. If the guest is not going to physically be at NIH, the Adobe signature function may be used (**NOT** a script font). A picture of a signature and electronic signature are not acceptable.

STEP 3: Maintain Signed Form

- An original copy of each agreement form must be maintained by the PI clinical team adhering to the [NIH 36 CFR Chapter XII Subchapter B – Records Management policy](#).

STEP 4: Submit Copy of Signed Form

- A delegate of the clinical team or lab/branch administrative staff person must submit a copy of the signed form for central tracking purposes via the [Office of the Clinical Director \(OCD\) Requests Portal](#).
 - The signed form will be maintained and active for a period of one year. After this time a returning guest must review the form and sign a new agreement form following the procedures detailed above.